



Attorney General Roy Cooper
North Carolina Department of Justice

NCDOJ appreciates the opportunity to express our concerns regarding the draft language circulated in the Pharmaceutical Liability subcommittee of Senate Judiciary I. Broadly, the NC Department of Justice has several concerns with the drafted legislation circulated at the meeting on February 29th. The effect of the bill is that it unnecessarily limits actions brought by the State of NC on behalf of consumers and taxpayers against pharmaceutical companies when a wrong has occurred. Because distribution of these drugs is nationwide, most actions brought by states are done in collaboration with other states and/or with Federal law enforcement authorities. If restrictions or limits are put on our ability to recover on behalf of harmed consumers and taxpayers, these multistate actions will continue, but North Carolina may not be able to take part. Every state other than Michigan will be able to recover for expenses associated with at worst harmful or at best unnecessary drugs, yet North Carolina as a state (for expenditures made on behalf of state patients, such as those in prisons or mental health facilities) and its consumers will be barred or restricted, even those the same exact drug purchases were made.

More specifically, some of our concerns include:

- (1) The bill in its current form is close to the Michigan statute that was held to bar Medicaid fraud recoveries in that state. With respect to drug products, the Michigan statute, MCLS § 600.2946(5), provides that a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved by the FDA and its labeling was in compliance with the FDA's approval. However, the liability shield does not apply if the defendant intentionally withheld from or misrepresented to the FDA information it was required to submit, and the drug would not have been approved (or its approval withdrawn) if that information had been accurately submitted. In effect, Michigan's drug liability shield creates a rebuttable presumption against liability; that presumption can be rebutted if the defendant intentionally withheld or misrepresented certain information to the FDA.

Similarly, N.C. Draft Bill 2011-TG-14A[v.1], § 99B-12(a) provides that in a product liability action against a manufacturer or seller, a manufacturer or seller is entitled to a rebuttable presumption that the drug was safe and effective, and the manufacturer or seller is not liable, if the drug was approved by the FDA and its labeling was in compliance with the FDA's approval. The presumption may be rebutted only by clear

and convincing evidence.^[1] However, the liability shield does not apply if the claimant proves by a preponderance of the evidence that the manufacturer or seller intentionally withheld from or misrepresented to the FDA information material to the drug's approval, in violation of applicable regulations as determined by final agency action, and that the information is relevant to the claimant's harm.

The Michigan law and the N.C. Draft Bill are very similar in their effect. Indeed, certain aspects of the N.C. Draft Bill may make the non-liability presumption even more difficult to rebut in North Carolina than it would be under the Michigan statute. In particular, under proposed 99B-12(b)(2), a necessary predicate to setting aside the non-liability presumption is the FDA taking a final agency action determining that the defendant intentionally withheld from or misrepresented to the FDA certain information. Further, as set forth below, the non-liability exceptions in sections (c) and (d) of the N.C. Draft Bill are not effective.

- (2) The language in § 99B-12 (c) in draft 14A of the bill is not effective at excepting North Carolina False Claims Act cases from the immunity bar. Subsection (c) in its current form could bar any False Claims Act case that is based on allegations that the product was not safe or effective or that the manufacturer failed to provide an adequate warning. This could be a severe limitation because many of our pharmaceutical Medicaid fraud cases include such allegations. It would invite litigation on the question of whether the False Claims Act action were "based" on this allegation.
- (3) Neither subsection (c) nor (d), in draft 14A of the bill, provides any exception for the important work of the North Carolina Attorney General's Office enforcing laws other than the False Claims Act. In particular, the Attorney General's Office would be barred from litigating and resolving claims under North Carolina's Unfair and Deceptive Trade Practices Act. Importantly, several of these cases were drug cases founded on the very same facts that often form the basis for False Claims Act cases. It would not be in the best interests of the State to have only a partial recovery of its damages where several State agencies have been victimized by a fraudfeasor's conduct. Moreover, it would not be in the best interests of the State to limit the legal tools available to Attorney General's Office, and force it to rely solely on the False Claims Act in the pharmaceutical drug context. For a variety of reasons it may be preferable to use other legal tools such as the Unfair and Deceptive Trade Practices Act or a common law fraud cause of action. The Attorney General's Office should be allowed to use its judgment and discretion to determine which legal theories best serve the interests of the State in a particular case.
- (4) The exemption in subsection (d) is flawed because (1) it only preserves authority to pursue some off-label cases, not other types of cases, and (2) even with respect to the off-label cases, it is insufficient because the new, burdensome requirements it would

^[1] "The clear and convincing evidence standard is greater than a preponderance standard required in most civil cases" Schenk v. HNA Holdings, 170 N.C. App. 555, 560 (2005).

add. First, the consumer Protection Division brings cases against pharmaceutical companies that are for claims other than off-label marketing. Second, it imposes new and burdensome requirements. Currently, off-label marketing itself is an unfair/deceptive trade practice and there is no need to prove “use” or that use was the “proximate cause of injury.” Currently, all we have to prove is the marketing. But this section would require that both of these other things be proved by a preponderance of the evidence in order for an off-label claim to lie, which would make it significantly more difficult to prove both a violation, as well as to prove penalties etc.